

**Abstract**

A combination dilatation and drug delivery device includes a flexible catheter, a drug delivery sheath mounted to a distal end region of the catheter and a dilatation balloon also mounted to the catheter and contained within a compartment formed by the sheath. The sheath is radially expandable by supplying a liquid therapeutic agent to the compartment under a moderate pressure. The dilatation balloon is expandable by providing a dilatation fluid to the balloon under a much higher pressure. The sheath can be formed of a highly elastic material or can be made quite thin, and in either case is mounted independently of the dilatation balloon. Thus when radially expanded, the sheath is moved into a conforming contact with surrounding vascular tissue. The conforming contact protects tissue and the therapeutic agent from exposure to blood, and more effectively confines the therapeutic agent to the intended treatment area. The sheath either is naturally porous or is provided with multiple pores, whereby the therapeutic agent perfuses through the sheath into the surrounding tissue.